# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/881,736 | 06/18/2001 | Michael Glotzer | 0652.2260001/EKS/AES | 8755 |

26111 7590 01/24/2006

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

| EXAMINER | |
|---|---|
| LI, RUIXIANG | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | |

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/881,736 | GLOTZER ET AL. | |
| | Examiner | Art Unit | |
| | Ruixiang Li | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,12,45,46,48-57,59-64 and 67-77* is/are pending in the application.

4a) Of the above claim(s) *1-6,12 and 74-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45, 46, 48-57, 59-64, 67-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 11/24/2005 has been entered in full. Claims 45, 54, 55, 61, 64, 70-73 have been amended. Claims 1-6, 12, 45, 46, 48-57, 59-64, and 67-77 are pending. Claims 45, 46, 48-57, 59-64, 67-73 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### Withdrawn Objections and/or Rejections

The rejection of claims 45, 46, 48-57, 59-64, 67-73 under 35 U.S.C. 112, 2nd paragraph as being indefinite has been withdrawn in view of amended claims.

### Claim Rejections under 35 U.S.C.§112, 1st Paragraph, Scope of Enablement

The rejection of claims 45, 46, 48-57, 59-64, and 67-73 under 35 U.S.C. 112, first paragraph for scope of enablement is maintained.

At the bottom of page 17 of Applicants' response, Applicants argue that the specification has provided sufficient guidance for one of ordinary skill in the art to make and use the CYK-4 variants in the claims at issue without undue experimentation and that the present application enables the full scope of the claims as presently amended.

Applicant's argument has been fully considered, but is not deemed to be persuasive because claims 45, 54, and 64 recite variants of human CYK-4 (SEQ ID NO: 2) and murine CYK-4 (SEQ ID NO: 4) that are encoded by nucleic acids hybridizing under stringent conditions to a polynucleotide having a nucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 3. Claims 48, 59, and 67 recite variants of human CYK-4 (SEQ ID NO: 2). The specification only provides a single species of CYK-4 for human CYK-4 of SEQ ID NO: 2 and murine CYK-4 of SEQ ID NO: 4. The specification does not provide sufficient guidance and/or working examples to make those variants that have the same functional activity as human CYK-4 of SEQ ID NO: 2 and murine CYK-4 protein of SEQ ID NO: 4 and to use those variants that do not have the same functional activity as human CYK-4 of SEQ ID NO: 2 and murine CYK-4 protein of SEQ ID NO: 4. The prior art at the time when the instant application was filed does not teach additional CYK-4 proteins that play critical roles in cytokinesis. Moreover, the state of the art is such that determining the specificity of hybridization is empirical by nature and the effect of mismatches is unpredictable, as taught by Wallace et al. (*Methods Enzymol.* 152:432-443, 1987) and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Edition, 1989, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, page 11.47). It is well known in the art that hybridisation yields structurally related, but functionally different nucleic acids. Thus, it would take undue experimentation for one skilled in the art to make and use the claimed methods.

At the 2nd paragraph of page 18 of Applicants' response, Applicants argue that the

claims recite that the CYK-4 variants must contain a specific protein domain relevant to the claimd method. Applicants submit that Fig. 3D illustrates the correspondance of these conserved domains between the C. elegans CYK-4 protein and human CYK-4, indicating which amino acid residues are critical for promoting GTP hydrolysis by a Rho family GTPase and which amino acid residues are critical for promoting the binding of CYK-4 to human CYK-4 and human MKLP1.

Applicant's argument has been fully considered, but is not deemed to be persuasive because the specification discloses does not disclose the GTPase activating protein domain and the domain that binds MKLP1 subfamily proteins. Fig. SD shows the positional cloning strategy of the cyk-4 locus; it does not show the GTPase activating protein domain or the domain that binds MKLP1 subfamily proteins.

At the top of page 20 of Applicants' response, Applicants argue that amended claims 45, 54, and 64 recite a specific function that the CYK-4 protein, fragment, or variant used in each claimed method must exhibit.

Applicant's argument has been fully considered, but is not deemed to be persuasive because neither the specification discloses nor the claims recite a defined functional domain for the CYK-4 protein, fragment, or variant. Reciting a function for a fragmet or a variant without defining the structural domain does not provide sufficient guidance for one of skilled in the art to make the functional fragment or variant.

At the 2nd paragraph of page 21 of Applicants' response, citing a reference of Van Aelst et al., Applicants argue that the GAP domain recited in claim 45 was known to those of skill in the art at the time of filing of the application. This is not found to be persuasive because the cited art does not teach the defined amino acid sequence of the GAP domain of the human CYK-4 polypeptide of SEQ ID NO: 2.

**Claim Rejections under 35 U.S.C.§112, 1st Paragraph, Written Description**

The rejection of claims 45, 46, 48-57, 59-64, and 67-73 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

At page 23 of Applicants' response, Applicants argue that amended claims 45, 54, and 64 recite that the CYK-4 protein, fragment, or variant contains a specific protein domain relevant to the method recited in the claims. Applicants also argue that amended claims 45, 54, and 64 recite the specific function exhibited by the CYK-4 protein, fragment, or variant recited in each claim.

Applicant's argument has been fully considered, but is not deemed to be persuasive because neither the specification discloses nor the claims recite a functional domain for the CYK-4 protein, fragment, or variant. It is noted that only description of what a

compound does without disclosure of the chemical structure of the compound, as is the case here, is not sufficient to satisfy the written description requirement under 35 U.S.C. §112, first paragraph.

**Claim Objection —Minor Informality**

The objection to claims 45, 46, 51-57, and 60-64, and 67-73 for reciting non-elected subject matter (murine CYK-4 of SEQ ID NO: 4) is maintained because no generic claim is allowable yet. Appropriate correction is required.

**Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li, Ph.D.
Primary Examiner
January 20, 2006